



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,296	05/24/2005	Andreja Vukmirovic	BPPG-32982A/LEK	9213
7590 06/23/2009				
Mark S. Graham, Esq. LUEDEKA, NEELY & GRAHAM, P.C. P.O. Box 1871 Knoxville, TN 37901				
EXAMINER				
HOLLOMAN, NANNETTE				
ART UNIT		PAPER NUMBER		
1612				
MAIL DATE		DELIVERY MODE		
06/23/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/521,296

Applicant(s)

VUKMIROVIC ET AL.

Examiner

NANNETTE HOLLOMAN

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2009.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 19-21 is/are pending in the application.
4a) Of the above claim(s) 14, 15 and 21 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-13, 19 and 20 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Applicants' arguments, filed March 06, 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Election/Restrictions

Newly submitted claim 21 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Group I, claim(s) 1-15 and 19-20, drawn to a stable pharmaceutical composition of erythropoietin.

Group II, claim(s) 21, drawn to a method for the treatment of diseases.

The technical feature linking the claims is EPO and PVP. Prior art exists which causes the compound in the current application to lack a special technical feature. In this case Woog et al. (US Patent No 4,992,419) discloses a composition consisting of EPO and PVP (Kollidon 12 PF) (see table 1, composition S1)

As a result, no special technical feature exists among the different groups because the inventions in Groups I and II fail to make a contribution over the prior art and are therefore not "special."

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for

prosecution on the merits. Accordingly, claim 21 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

Claims 1-13 were rejected under 35 U.S.C. 102(b) as being anticipated by Woog et al. (US Patent No. 4,992,419). This rejection is maintained.

Applicant's Arguments

Applicant argues the transition phrase "consisting essentially of" partially closes the claims to exclude additional materials which materially affect the basic and novel characteristics of the claimed composition. Applicant further argues Woo et al. disclose urea as the main EPO stabilizer. Applicant's arguments have been fully considered but they are not persuasive.

Examiner's Response

The term "consisting essentially" is inadequately described by the instant specification, since it fails to contemplate the exclusion of any particular ingredients as implied therein; nor does it provide any criteria for determining if a given ingredient "materially affects the basic or novel characteristics of the invention". Particularly at page 4, lines 10-25 of the instant specification, Applicant discloses a preferred embodiment of a composition "comprising" components a.-c. and optionally d. and e. Woog et al. discloses in EXAMPLE 5, column 6 an EPO composition which does not contain urea as a stabilizer. Therefore, Woog et al. encompass the limitation of the

instant claims.

Claim Rejections - 35 USC § 103

Claim 16 was rejected under 35 U.S.C. 103(a) as being unpatentable over Woog et al. (US Patent No. 4,99,419) as applied to claims 1-13 above, and further in view of Cymbalista (US Patent No. 4,647,454). This rejection is maintained and is further applied to new claims 19-20.

Applicant's Arguments

Applicant argues Woog teaches a composition in which urea is the principal stabilizer for EPO. Applicant further argues Cymbalista uses PVP to stabilize interferon β , not EPO and one of ordinary skill would recognize that a stabilizer which is effective for one protein may be inappropriate for stabilizing a different protein. Applicant's arguments have been fully considered but they are not persuasive.

Examiner's Response

In regard to Woo et al., see Examiner's Response supra. Cymbalista was used to disclose that PVP has been shown to be a highly effective stabilizer of protein (column 3, line 67 and Tables 1-6).

It is *prima facie* obviousness to select a known material based on its suitability for its intended use. Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known

function. MPEP 2144.07. Therefore, it would have been obvious to have used PVP as the sole stabilizer of Woo et al. motivated by the desire to use a material known for its stabilizing properties.

In addition, in KSR v. Teleflex, 82 USPQ2d 1385, 1397 (U.S. 2007), the Supreme Court has held that when there is market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person has good reason to pursue known options within his or her technical grasp. Under these conditions, "obviousness to try" such options is permissible. In this instance, a market pressure exists in the medical/pharmaceutical industries to achieve long-term EPO stabilization. Accordingly, it would have been obvious to have tried the stabilizer PVP in the formulation of Woo et al. motivated by the desire to achieve maximum stability as disclosed by Cymbalista.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANNETTE HOLLOMAN whose telephone number is (571) 270-5231. The examiner can normally be reached on Mon-Fri 800am-500pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. H./
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612

Application/Control Number: 10/521,296
Art Unit: 1612

Page 7